Plaque excision with the Silverhawk catheter: Early results in patients with claudication or critical limb ischemia

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Objective: **This study was conducted to detail the early experience after infrainguinal atherectomy using the Silverhawk plaque excision catheter for the treatment of symptomatic peripheral vascular disease.**

Methods: **A prospective database was established in August 2004 in which data for operations, outcomes, and follow-up were recorded for patients undergoing percutaneous plaque excision for peripheral arterial occlusive disease. Society for Vascular Surgery (SVS) ischemia scores and femoropopliteal TransAtlantic Inter-Society Consensus (TASC) criteria were assigned. A follow-up protocol included duplex ultrasound surveillance at 1, 3, and 6 months and then yearly thereafter. Standard statistical analyses were performed.**

Results: **During a 17-month period, 66 limbs of 60 patients (37 men [61.7%]) underwent 70 plaque excisions (four repeat procedures). Indications included tissue loss based on SVS ischemia at grades 5 and 6 (25/70), rest pain at grade 4 (22/70), and claudication at grades 2 to 3 (23/70). The mean lesion length was 8.8 ± 0.7 cm. The technical success rate was 87.1% (61/70). Adjunctive treatment was required in 17 procedures (24.3%), consisting of 14 balloon angioplasties and three stents. Femoropopliteal TASC criteria included 5 TASC A lesions, 14 TASC B lesions, 32 TASC C lesions, and 19 TASC D lesions. Although 17 plaque excisions included a tibial vessel, no patient underwent isolated tibial atherectomy. The mean increase in ankle-brachial index was 0.27 ± 0.04 and in toe pressure, 20.3 ± 6.9 mm Hg. Mean duplex ultrasound follow-up was 5.2 months (range, 1 to 17 months). One-year primary, primary assisted, and secondary patency was 61.7%, 64.1%, and 76.4%, respectively. Restenosis or occlusion developed in 12 patients (16.7%) and was detected at a mean of 2.8 ± 0.7 months. Restenosis or occlusion was significantly more common ($P < .05$) in patients with TASC C and D lesions compared with patients with TASC A and B lesions. Six (8.3%) of 12 patients underwent reintervention on the basis of duplex ultrasound surveillance results. Four (33.3%) of 12 patients experienced reocclusion during the same hospitalization, and amputation and open revascularization were required in two patients each.**

Conclusions: **Percutaneous plaque excision is a viable treatment option for lower extremity revascularization. Outcomes are related to ischemia and lesion severity. Patency and limb salvage rates are equivalent to other endovascular modalities. (J Vasc Surg 2007;45:25-31.)**

Traditional surgical therapies for infrainguinal peripheral arterial occlusive disease have centered on bypass of diseased vessels to distal targets. These procedures are often complicated by lack of suitable conduit, high rates of wound complications, and have a reintervention rate of up to 28%.[1,2] With the advances in catheter-based interventions, endovascular techniques are commonly being used as alternatives to open infrainguinal bypass procedures. To date, infrainguinal disease has been managed, with varying degrees of success, with balloon angioplasty, stenting, cryoplasty, laser, and excisional atherectomy.

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Competition of interest: Dr Shames has received funds for device training and for speaking on behalf of Fox Hollow Technologies at regional meetings.

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In a study detailing long-term patency of superficial femoral artery (SFA) angioplasty and stenting, primary patency was demonstrated in 52% of patients at 5 years of follow-up.[3] Angioplasty of infragenicular arteries has also been practiced with some degree of success. Although primary patency was only 23.5% for infragenicular vessels, limb salvage was 77.3% in one series.[4] Both studies found that periprocedural failure or resultant occlusion, or both, was dependent on Transatlantic Inter-Society Consensus (TASC) criteria. TASC D lesions demonstrated lower patency rates and lower rates of limb salvage for below knee lesions, and primary patency of SFA lesions was lower in TASC C and D lesions.[3,4]

Our purpose in this report was to add to the mounting body of data on the Silverhawk Plaque Excision Catheter (Fox Hollow Technologies, Inc, Redwood City, Calif) by publishing our early results. In addition, by using reporting standards common to vascular surgeons, including the Society for Vascular Surgery (SVS) ischemia grading system and the TASC criteria for femoropopliteal lesions, we sought to identify risk factors for reocclusion. We hypothesized that TASC criteria for femoropopliteal lesions would assist in predicting early reocclusion after successful

(<30% residual stenosis) plaque excision with the Silverhawk catheter.

METHODS

Patient population. From August 2004 to January 2006, all patients who were treated with the Silverhawk Plaque Excision Catheter were enrolled in a prospective database. Patients scheduled for atherectomy in whom the lesion could not be crossed or in whom the Silverhawk device could not be passed were excluded from analysis. All plaque excisions were performed by a single vascular surgeon (M. L. S.). Patients with isolated tibial infrageniculate disease were not considered for this study.

Data on demographics, operative details, outcomes, and follow-up were gathered from hospital, office, and vascular laboratory records and included in the computerized database. This study was not sponsored directly by industry, but some patients in the series were treated as a part of physician training programs sponsored by Foxhollow, Inc.

Atherectomy technique. Atherectomy was performed in the operating room using portable imaging equipment (OEC 9800M; General Electric Healthcare, Waukesha, Wisc). Procedures were performed via a contralateral (40/70) or ipsilateral (30/70) approach through a 7F introducer sheath. Arteriography was performed initially to determine the extent of disease and delineate tibial runoff in patients where computed tomography angiography or magnetic resonance angiography was not available preoperatively.

A combination of a straight stiff Glidewire (Terumo Medical Corp, Somerset, NJ) and angled Glidecath (Terumo Medical Corp) were used to traverse occluded vessels. Once the lesion was crossed and re-entry into the true lumen was confirmed with contrast injection, a 0.014-inch guidewire was placed. Systemic anticoagulation was initiated with intravenous heparin sodium (100 IU/kg).

The Silverhawk device was then selected based on the target vessel size and location. For tibial lesions or vessel diameter <3 mm, an SS or ES device was used, and a vessel diameter of 3 to 5 mm required an SX device. Calcified lesions or distal popliteal lesions were treated with an MS device and SFA lesions, with an LS, LS-F, or LX catheter.

After atherectomy, focal dissections without hemodynamic disturbance were treated with low-pressure (4 atm) balloon dilation to approximate the intima. For significant residual stenosis >30% not amenable to repeat atherectomy or hemodynamically significant dissections, stenting was performed with nitinol self-expanding stents. Pressure gradients or intraoperative duplex evaluation was performed if hemodynamic improvement was questionable. All patients were treated with clopidogrel bisulfate, 75 mg daily, after intervention.

Hemodynamic evaluation. Arterial testing before and after intervention was performed at a laboratory registered by the Inter-societal Committee for the Accreditation of Vascular Laboratories. Atherectomy site surveillance was initiated in the outpatient clinic with clinical examination ≤2 weeks, and ankle-brachial index (ABI) and duplex ultrasound arterial imaging at 1, 3, and 6 months, and then yearly. Indications for repeat intervention included recurrent symptoms with a drop in ABI of >0.15, duplex-detected stenosis (peak systolic velocity 300 cm/s, velocity ratio across the lesion of 3.5), or >70% stenosis by CT angiography, magnetic resonance angiography, or contrast arteriography.

Data analysis. The attending surgeon reviewed all intraoperative angiograms, and lesions were assigned a femoropopliteal TASC category. Success of plaque excision was defined according to the SVS and the International Society for Cardiovascular Surgery reporting standards.[5]

Statistical analysis. The tests used were Student's *t* test to evaluate continuous variables (Excel, Microsoft Corp, Redmond, Wash), Fisher's exact test for binomial variables (http://www.matforsk.no/ola/fisher.htm), Kaplan-Meier calculations and life tables (http://www.hutchon.net/Kaplan-Meier.htm), and log-rank tests for comparison of patency results (http://bioinf.wehi.edu.au/software/russell/logrank/). All results were expressed as mean ± SEM when appropriate. $P < .05$ were considered significant.

RESULTS

During the study period, 70 plaque excisions were done in 66 limbs of 60 patients (37 men, 61.7%), including six patients with bilateral disease and four patients with recurrent disease. Twenty-seven patients (45.0%) had diabetes mellitus, 22 patients (36.7%) were smoking at the time of their intervention, 6 (10.0%) were in end-stage renal failure requiring dialysis, and 6 (10.0%) had failed previous lower extremity bypass procedures (one SFA stent).

Indications for intervention included tissue loss represented by SVS ischemia grades of 5 and 6 (25/70; 35.7%); rest pain, SVS grade 4 (22/70; 31.4%), and claudication, SVS grades 2 to 3 (23/70; 32.9%). Mean preoperative ABI of the affected limb was 0.53 ± 0.03, and mean toe pressure was 41.3 ± 5.7 mm/Hg.

Atherectomized arterial segments included the common femoral artery in 1, the superficial femoral artery (SFA) in 52, the popliteal artery in 29, and the tibial arteries in 17. Mean plaque excision length was 8.9 ± 0.8 cm (range, 2 to 30 cm), and 23 plaque excisions (32.9%) were ≥10 cm. Local anesthesia was used in 40 procedures (57.1%).

Femoropopliteal TASC criteria included 5 TASC A lesions (7.1%), 14 TASC B lesions (20.0%), 32 TASC C lesions (44.3%), and 19 TASC D lesions (27.1%). Fourteen procedures (20.0%) required adjunctive balloon angioplasty at the site of plaque excision, and three procedures (4.3%) required adjunctive stent placement.

Table I. Outcomes of failed peripheral plaque excision

SVS ischemia grade	*TASC*	*Time to failure (months)*	*Mode of failure*	*Treatment*	*Limb loss*
4	D	3	Thrombosis	SFA stent	No
4	C	4	Restenosis	Repeat atherectomy	No
5	D	6	Thrombosis	Repeat atherectomy	No
5	C	4	Thrombosis	None	No
6	D	8	Thrombosis	Bypass	No
6	C	0	Thrombosis	Repeat atherectomy	No
6	C	2	Thrombosis	Repeat atherectomy and SFA stent	No
6	C	0	Thrombosis	Amputation	Yes
4	D	1	Thrombosis	Bypass	No
6	D	0	Thrombosis	Bypass	Yes
4	D	2	Thrombosis	None	No
4	D	0	Thrombosis	Bypass	No

SVS, Society of Vascular Surgery; *TASC,* TransAtlantic Inter-Society Consensus; *SFA,* superficial femoral artery.

The initial technical success rate was 87.1%. Distal embolization, which resulted in the failure of five procedures (7.0%), was treated successfully with either suction embolectomy or intravascular tissue plasminogen activator. There were four repeat atherectomies (5.7%). The average time for plaque excision after crossing the lesion was 40 minutes (range, 15 to 90 minutes). The Silverhawk catheter was reinserted a mean of four times (range, 1 to 7), with four to six passes per insertion.

The mean increase in ABI was 0.27 ± 0.04 and the mean increase in toe pressure was 21.6 ± 7.0 mm/Hg after plaque excision. Of the 51 patients with ABIs completed before discharge, 26 (51.0%) had an ABI in the affected limb of >0.8, and 12 (46.2%) had critical limb ischemia (CLI) preoperatively.

Average length of stay was 5.7 ± 1.0 days (range, 0 to 38 days), but for 32 procedures (45.7%), patients remained in the hospital for ≤23 hours. Mean length of stay was lengthened by patients who underwent atherectomy for CLI as part of a prolonged hospital stay.

There were no deaths at 30 days. Major procedural complications occurred in three patients (5.0%), including a perforated common iliac artery during a procedure that was repaired with covered stent placement, a myocardial infarction, and an operative intervention for a groin hematoma. There were no perforations of treated vessels. Three patients required further open revascularization owing to persistent tissue ischemia ≤1 month of the atherectomy, even with angiographically patent atherectomy sites. Of the four patients who experienced in-hospital reocclusion, three who had SFA atherectomy only underwent subsequent open distal bypass for ongoing critical ischemia despite angiographically patent SFAs, and two required amputation during the same hospitalization.

Twelve plaque excisions (17.1%) reoccluded (n = 11) or restenosed (n = 1) and were detected at a mean of 2.8 ± 0.7 months (range, 0 to 10 months), and six underwent reintervention for restenosis detected by duplex ultrasound imaging (Table). Forty-six patients (76.7%) entered into a duplex ultrasound surveillance protocol, and mean follow-up was 6.1 months (range, 1 to 20 months). Primary, primary assisted, and secondary patency for the entire cohort was 61.7%, 64.1%, and 76.4% at 1 year. For SVS grades 2 to 3, primary and secondary patency was significantly improved compared with SVS grades 4 to 6 ($P < .025$, and $P < .05$, Fig 1). Similarly, when compared by TASC criteria, 6-month primary patency was significantly less in TASC C and D lesions than in TASC A and B lesions ($P < .025$, and $P < .10$, Fig 2).

Four (33.3%) of 12 patients experienced reocclusion during the initial hospitalization, and two required amputations. A total of four patients (6.7%) underwent amputation (3 below knee amputations; 1 above knee amputation) of the affected limb. Half of these patients had patent atherectomy sites but required amputation for ongoing ischemia without further revascularization options. Two patients who later underwent amputation initially refused amputation and were offered atherectomy as a last-ditch alternative. One of these patients had extensive forefoot tissue loss without options for tissue reconstruction.

Four patients also required distal open revascularization; three of these had angiographically patent atherectomy sites. For patients with CLI (SVS ischemia grades 4 to 6), limb salvage was 86.2% at 12 months (Fig 3). Patients with TASC C or D lesions (5 and 7 lesions, respectively) were more likely to reocclude than those with TASC A and B lesions (0 and 0 lesions). In addition, patients who experienced reocclusion had a significantly higher mean SVS ischemia grade (4.9 ± 0.3 vs 3.8 ± 0.1; $P = .006$). Although no patient underwent isolated tibial atherectomy, the inclusion of tibial atherectomy (17 total patients; 5 reocclusons) in conjunction with atherectomy of other infrainguinal arteries demonstrated a significant increase in the rate of reocclusion ($P = .03$).

DISCUSSION

The use of endovascular procedures for the treatment of peripheral arterial occlusive disease is widespread and

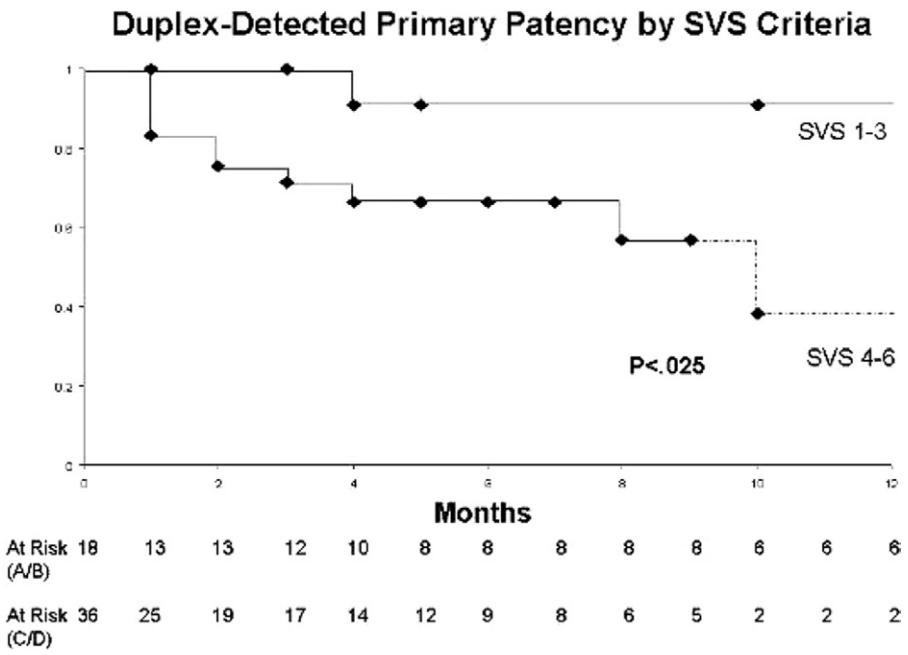

Fig 1. Kaplan Meier analysis of primary patency after plaque excision by SVS ischemia grades. Patients with SVS ischemia grades 4-6 had statistically decreased patency compared with patients with ischemia grades 1-3.

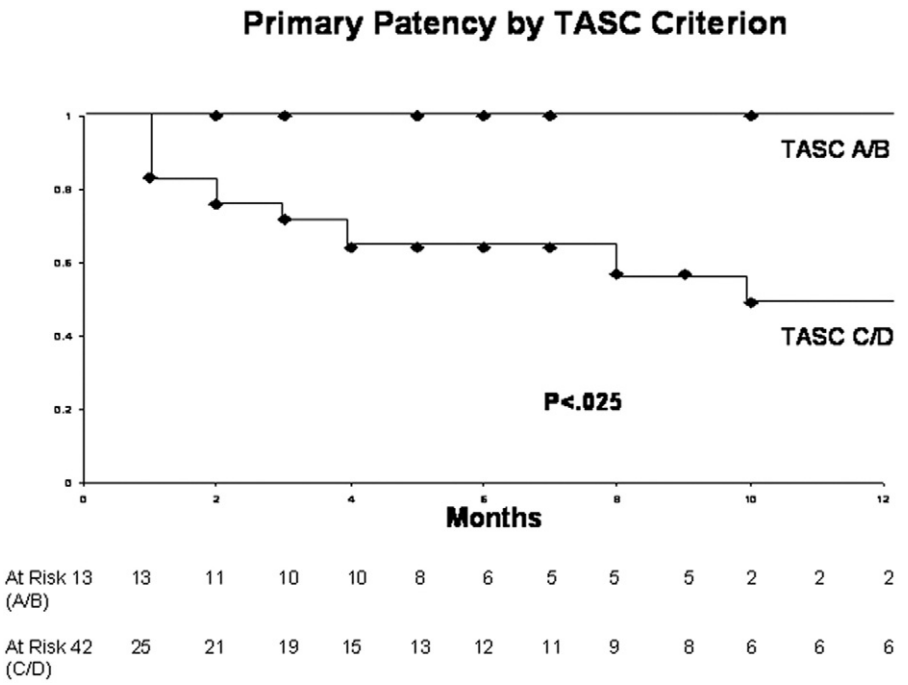

Fig 2. Primary patency by TransAtlantic Inter-Society Consensus *(TASC)* criteria.

increasing in frequency. A recent audit from our vascular group documented a 62% increase in the endovascular treatment of iliac and infrainguinal lesions during the past 6 years; the greatest increase being a 10-fold increase in infrainguinal interventions.[6] Despite this trend, several studies report marginal long-term patency and high reintervention rates for angioplasty, subintimal angioplasty, and SFA stent placement.[7]

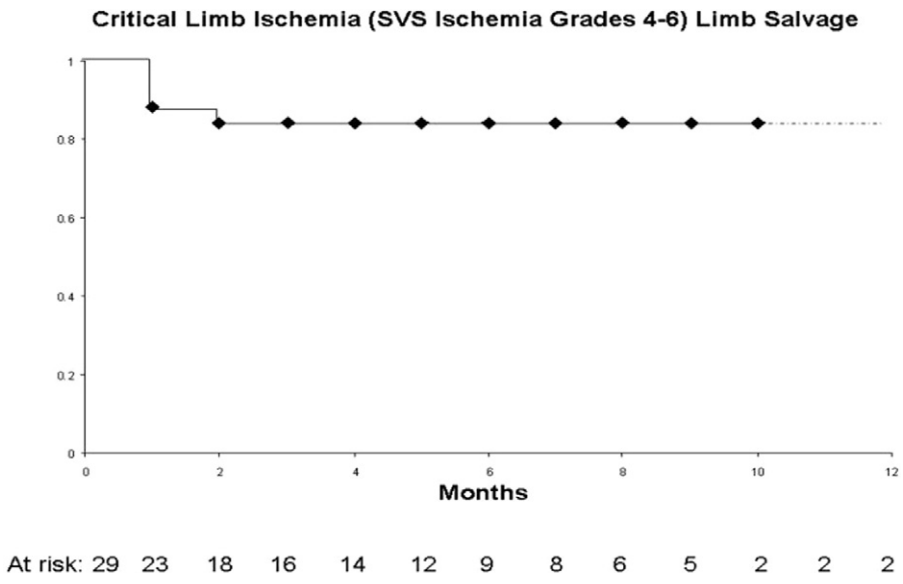

Fig 3. Kaplan Meier analysis of limb salvage rates following plaque excision in patients with critical limb ischemia SVS 4-6.

The Silverhawk catheter is a modification of earlier atherectomy devices. Prior catheters had balloons built into their design and were of higher profile. This new generation device enables improved luminal gain without the resultant barotrauma associated with balloon angioplasty and stent placement. Its low-profile monorail design facilitates traversal of long-length lesions and repetitive plaque excision. Catheters are sized to the target vessel lumen for optimal results.

Previously published reports about the use of this catheter have conveyed relatively favorable results. Zeller et al[8] reported an 80% patency in primary-treated lesions at 6 months. The reported mean lesion length treated by plaque excision was short (4 cm in native vessels), and the patient cohort was composed primarily of SFA lesions in patients with claudication. Atherectomy for patients with CLI has also had encouraging results by improving foot perfusion to avoid major amputations. Data from a prospective evaluation of plaque excision in 69 patients with CLI demonstrated less extensive amputation than predicted preoperatively in 82% of treated patients at 6 months.[9] Results from the Talon Registry (Treating Peripherals with Silverhawk: Outcomes Collection), a multicenter Web-based database of Silverhawk-treated patients, reported a 1-year freedom from target lesion revascularization of 81%; however, plaque excision length was short, and 70% of patients were treated for claudication symptoms.[10]

The data presented in this report are unique in a number of ways. In contrast to prior studies, the patient cohort included a number of patients with long-segment plaque excision as well as a large percentage of patients with CLI. Long-segment plaque excision is feasible. Atherectomy was offered to all patients with lifestyle-limiting claudication, rest pain, or tissue loss presenting to the primary investigator (M. L. S.) with superficial femoral artery occlusive disease. Decisions about actual treatment were made after angiography and successful crossing of target lesions.

In our early experience, some patients with focal disease were treated with primary angioplasty, and heavily calcified lesions were treated with primary stenting. Lesions not amenable to endovascular therapy (lesions that could not be crossed and complex superficial and tibial occlusive disease) were treated with standard bypass procedures. During the study period, 61% (70/115) of the ischemic limbs presenting to the primary author were treated with percutaneous plaque excision, 10 patients with percutaneous angioplasty only (2 cryoplasty), and four with primary stent placement. Twenty lesions could not be crossed. These patients all were treated with bypass procedures. An additional 11 patients were treated with bypass surgery without attempts at percutaneous revascularization.

Approximately two thirds of patients who underwent plaque excision for the indications of either rest pain or tissue loss had SVS ischemia grades of ≥ 4, and this also represents a change from published reports. Patients undergoing plaque excision demonstrated an average increase of 0.2 in ABI and 20 mm Hg in toe pressure after intervention, comparable with results reported after balloon angioplasty or stent placement.[4,11] Clinical improvement was apparent in most cases, only four patients required bypass for ongoing ischemia despite patent atherectomized segments. These cases likely reflect inadequate hemodynamic improvement for wound healing in patients with significant tissue loss.

Atherectomy, like other endovascular interventions, can be performed without general anesthesia, reduces the complications of surgical bypass, and shortens length

of stay. Our overall complication rate was 10.0% at 30 days, with no deaths. Two deaths (2.7%) occurred during the follow-up period, perhaps reflecting the less invasive nature of endovascular therapy. Past studies have reported mortality rates of 20% to 27% at 1 year in CLI patients.[12] Our data compare favorably with the 5-year survival of 56% obtained with balloon angioplasty in CLI patients.[4] Longer follow-up is needed to establish a survival benefit in this group of patients; clearly, however, resolution of clinical ischemic symptoms and avoidance of limb amputation would lead to improved quality of life.

Our prolonged length of stay is a consequence of a number of procedures being performed on patients hospitalized for nonhealing wounds in whom length of stay was dictated by wound healing. Almost half (45.7%) of the patients were treated as outpatients, and 60% spent ≤2 days in the hospital.

In patients with CLI, 12-month primary patency was 36% and secondary patency was 62%. The demographic characteristics of the patient population may account for these results: 45% were diabetic, 37% continued to smoke, and 10% required hemodialysis. Despite the decreased patency, limb salvage rates at 86.2% at 1 year were comparable with both bypass and other percutaneous interventions.[4,12,13]

Reocclusion or restenosis after technically successful plaque excision occurred in a number of patients. Twelve atherectomies reoccluded or restenosed, and four occurred during the original hospital stay. These in-hospital reocclusions likely contributed to the short mean duration to reocclusion. Four reocclusions in our series were amenable to repeat percutaneous intervention, and an additional four were treated with surgical bypass. In accordance with a previous report detailing mid-term outcomes of atherectomy-assisted angioplasty, our cohort experienced reocclusion at a rate of 16.7% at 6 months.[14] We found that reocclusion rates were related to TASC criteria, and this parallels the experience of infrainguinal angioplasty. In the group treated with lesions classified as TASC A/B, 6-month primary and secondary patency was 100%. In contrast, TASC C/D lesions had only 64% primary and 74% secondary patency. Kudo et al[4] also determined that TASC D lesions were predictive of decreased patency after angioplasty for CLI. Although other authors have concluded that TASC criteria did not predict outcome after infrainguinal percutaneous intervention, we determined that TASC criteria did predict outcomes in our cohort of patients.[15]

Similarly, patients with more advanced disease, SVS grades 4 to 6, had significantly reduced primary and secondary patency at 6 months of 62% and 73% vs 100% and 100% for grades 2 to 3. The improvement after repeat intervention is an important factor, repeat interventions are generally well tolerated and are not usually more complicated than primary interventions.

Given the rate of reocclusion, we believe that duplex ultrasound surveillance is important after peripheral plaque excision. Our group has a substantial experience with protocol-driven duplex ultrasound surveillance, and we believe that these patients should be entered into such a protocol.[16-18] Half of the failures of plaque excision were detected and ultimately intervened upon based on duplex testing. As our indications continue to expand for plaque excision, duplex imaging will no doubt be increasingly important in surveillance as prior work on atherectomy demonstrated an increased rate of reocclusion and restenosis.[14]

This study is certainly not without limitations. All of the cases were performed at a single center by a single surgeon and therefore may not be reproducible. Patients were not compared with another treatment modality nor were they randomized. Not all patients participated in a follow-up surveillance protocol. Early results prohibit statements about the long-term adequacy of atherectomy for selected patients. The patient population was somewhat heterogeneous in that one third were patients with claudication, and difficulty arises when attempting to compare patients with claudication with those with CLI.

CONCLUSIONS

Plaque excision with the Silverhawk device is feasible in a wide spectrum of patients with peripheral arterial occlusive disease. Initial technical success rates are high, and periprocedural morbidity and mortality rates are lower than surgical bypass. Patency rates in patients with claudication and with TASC A and B lesions approach 100% at 1 year. In patients with CLI and more complex lesions (TASC C and D), primary patency rates are significantly reduced. Despite these findings, a number of lesions can be secondarily treated with endovascular techniques, improving assisted and secondary patency rates to 70%. Furthermore, limb salvage rates of 86% are equivalent to those reported after bypass and other endovascular interventions.[4,18] Although plaque excision can be considered for first-line treatment of claudication and CLI, further studies are warranted to determine the optimal treatment strategy in patients with CLI and complex lesions (TASC D) in whom surgical revascularization is not considered high risk.[19]

AUTHOR CONTRIBUTIONS

Conception and design: WK, MS, DB
Analysis and interpretation: WK, MS, PS, PA, BJ, MB, DB
Data collection: WK, PS, PA, MS
Writing the article: WK, MS, MB, DB
Critical revision of the article: MS, PA, DB
Final approval of the article: MS
Statistical analysis: MB, BJ, WK
Obtained funding: Not applicable
Overall responsibility: MS

REFERENCES

1. Gupta AK, Bandyk DF, Cheanvechai D, Johnson BL. Natural history of infrainguinal vein graft stenosis relative to bypass grafting technique. J Vasc Surg 1997;25:211-20; discussion 220-5.
2. Armstrong PA, Bandyk DF, Wilson JS, Shames ML, Johnson BL, Back MR. Optimizing infrainguinal arm vein bypass patency with duplex ultrasound surveillance and endovascular therapy. J Vasc Surg 2004;40: 724-30; discussion 730-1.
3. Surowiec SM, Davies MG, Eberly SW, Rhodes JM, Illig KA, Shortell CK, et al. Percutaneous angioplasty and stenting of the superficial femoral artery. J Vasc Surg 2005;41:269-78.
4. Kudo T, Chandra FA, Ahn SS. The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: a 10-year experience. J Vasc Surg 2005;41:423-35; discussion 435.
5. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
6. Keeling WB, Stone PA, Armstrong PA, Kearney H, Klepczyk L, Blazick E, et al. The impact of increasing endovascular intervention for claudication on vascular resident training. J Endovs Ther 2006;13:507-13.
7. Bates MC, AbuRahma AF. An update on endovascular therapy of the lower extremities. J Endovasc Ther 2004;11(Suppl II):II-107-27.
8. Zeller T, Rastan A, Schwarzwalder U, Frank U, Burgelin K, Amantea P, et al. Percutaneous peripheral atherectomy of femoropopliteal stenoses using a new-generation device: six month results from a single-center experience. J Endovasc Ther 2004;11:676-85.
9. Kandzari DE, Kiesz RS, Allie D, Walker C, Fail P, Ramaiah, et al. Procedural and clinical outcomes with catheter-based plaque excision in critical limb ischemia. J Endovasc Ther 2006;13:12-22.
10. McKinsey JF, Ramaiah VG, Runyon JP, Allie D, Kiesz S, McKinsey JF, Walker C, et al. 1 year results of treatment of infrapopliteal arterial occlusive disease using the Silverhawk Plaque Excision Device. Available at http://www.pvss.org/abstracts/wabs06/w0505.pdf. Accessed June 2006.
11. Schillinger M, Exner M, Mlekusch W, Haumer M, Rumpold H, Ahmadi R, et al. Endovascular revascularization below the knee: 6-month results and predictive value of C-reactive protein level. Radiology 2003; 227:419-25.
12. Bailey CM, Saha S, Magee TR, Galand RB. A 1 year prospective study of management and outcomes of patients presenting with critical lower limb ischaemia. Eur J Vasc Endovasc Surg 2003;25:131-4.
13. Balmer H, Mahler F, Do DD, Trller J, Baumgartner I. Ballon angioplasty in chronic critical limb ischemia: factors affecting clinical and angiographic outcome. J Endovasc Ther 2002;9:122-6.
14. Zeller T, Rastan A, Schwarzwalder U, Frank U, Burgelin K, Amantea P, et al. Midterm results after atherectomy-assisted angioplasty of below-knee arteries with use of the Silverhawk device. J Vasc Interv Radiol 2004;15:1391-7.
15. Clark TW, Groffsky JL, Soulen MC. Predictors of long-term patency after femoropopliteal angioplasty: results from the STAR registry. J Vasc Interv Radiol 2001;12:923-33.
16. Back MR, Novotney M, Roth SM, Elkins D, Farber S, Cuthbertson D, et al. Utility of duplex surveillance following iliac artery angioplasty and primary stenting. J Endovasc Ther 2001;8:629-37.
17. Roth SM, Bandyk DF. Duplex imaging of lower extremity bypasses, angioplasties, and stents. Semin Vasc Surg 1999;12:275-84.
18. Bandyk DF. Infrainguinal vein bypass graft surveillance: how to do it, when to intervene, and is it cost-effective? J Am Coll Surg 2002;194(1 Suppl):S40-52.
19. Feinglass J, Pierce WH, Martin GJ, Gibbs J, Cowper D, Sorensen M, et al. Postoperative amputation free survival outcomes after femoro-distal bypass grafting surgery. J Vasc Surg 2001;34:283-90.